DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 17, 2014

Covidien LLC
% Ms. Heather V. Nigro
Global Senior Director, Regulatory Affairs
15 Hampshire Street
MANSFIELD MA 02048

Re: K142048
Trade/Device Name: Emprint™ Procedure Planning Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2014
Received: July 30, 2014

Dear Ms. Nigro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142048

Device Name
Emprint Procedure Planning Application

Indications for Use *(Describe)*
The Emprint™ Procedure Planning Application is a stand-alone software product that allows physicians to visualize and compare CT imaging data. The display, annotation, and volume rendering of medical images aids intervention planning for video-assisted thoracoscopic surgery (VATS) and ablation procedures using the Emprint Ablation System. The software is not intended for diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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COVIDIEN

510(k) Summary

Date summary prepared: August 19, 2014

510(k) Submitter/Holder

Covidien, Inc.
15 Hampshire Street
Mansfield, MA 02048

Contact

Heather V. Nigro
Global Senior Director, Regulatory Affairs
Telephone: 508-452-1936
Fax: 508-452-1941
Email: heather.nigro@covidien.com

Name of Device

Trade Name:	Emprint™ Procedure Planning Application
Common Name:	Radiological Image Processing System
Classification Name:	System, Image Processing, Radiological (21 CFR §892.2050, Class II, LLZ).

Purpose of Submission

The purpose of this submission is to gain clearance for a new procedure planning application.

Predicate Devices

Emprint™ Procedure Planning Application described in this submission is substantially equivalent to the following commercially available predicate devices:

Trade Name:	LiverAnalysis/LiverViewer Software
Device Common Name:	Picture Archiving Communications System
510(k) Number:	K051528
Manufacturer:	MeVis

Trade Name:	Table
Device Common Name:	Radiological Image Processing System
510(k) Number:	K140093
Manufacturer:	Anatomage, Inc.

Device Description

The Emprint™ Procedure Planning Application is a stand-alone software product that is intended to be used to view and compare CT image sets. The system is composed of

image review and planning software and a Windows-based computer. The system includes tools that provide 3-D rendering of the image sets, pre-procedure planning of interventional thermal ablation procedures, and post-procedure review of interventional thermal ablation procedures. The Emprint™ Procedure Planning Application does not prescribe therapy and is not intended for the diagnosis or treatment of any disease. It does not control or alter the functions or parameters of any medical device and has no direct patient contact.

Intended Use

The Emprint™ Procedure Planning Application is a stand-alone software product that allows physicians to visualize and compare CT imaging data. The display, annotation, and volume rendering of medical images aids in the intervention planning for video-assisted thoracoscopic surgery (VATS) and ablation procedures using the Emprint Ablation System. The software is not intended for diagnosis.

Technological Characteristics

The Emprint™ Procedure Planning Application is a stand-alone software product installed on a Windows-based computer workstation. The system imports DICOM data from CT scanners and can display the images in standard axial, coronal, or sagittal views and render the images in 3-D views. The substantial equivalence of the Emprint™ Procedure Planning Application to the predicates is shown by similarity in intended use, indications for use, materials, and performance.

Principals of Operation

The Emprint™ Procedure Planning Application is composed of software running on a standard Windows-based computer that allows the user to import multiple DICOM compatible CT image sets, render them into 3-D and compare them. The software also provides tools to mark and measure anatomical features and to overlay anticipated thermal ablation zones as defined by the ablation tables associated with the Emprint Ablation System settings for a given type of tissue (provided in K133821 labeling and also included as an Attachment to this 510k Summary).

Performance Data

The Emprint™ Procedure Planning Application was tested in accordance with a test plan to evaluate all functions performed by the software as configured on the computer workstation. The system was tested and passed all criteria established by the design specifications and verification/validation test plans.

Substantial Equivalence Discussions

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the Emprint™ Procedure Planning Application has been

shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.